

Law Offices of
ANDRE A. ROUVIERE
Merrick Park Law Center
4070 Laguna Street
Coral Gables, Florida 33146
e-mail: Andre@Rouvierelawfirm.com

André A. Rouviere
Lissette B. Cruz

Telephone (305)774-7000
Fax (305)946-6121

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Joe Eaton
Barnes & Thornberg LLP
11 South Meridian Street
Indianapolis, Indiana 46204

Paul E. Asfendis
Gibbons P.C.,
One Pennsylvania Plaza,
37th Floor
New York, NY 10119-3701

RE: ROUVIERE v DEPUY/STRYKER

Dear Joe/Paul:

This letter serves as an attempt to resolve certain discovery disputes pending with Depuy's response to Plaintiffs Interrogatories. Please see below and provide a response within 10 days of this letter.

As to Depuy's response, both its answers and objections to the Plaintiffs first set of interrogatories, the Plaintiff provides the following:

Initially, **Depuy's Boilerplate objections**, listed below, are untimely, improperly pled and baseless. Accordingly, please withdraw your objections and provide full responses to all interrogatories (not "subject to and without waiving") to which these objections were asserted, including:

1. "Overly broad"
 - a. This objection was asserted for every interrogatory except No. 7;
 - b. In order to assert this objection, it requires specificity.
2. "Unduly burdensome"
 - a. (This objection was asserted for every interrogatory except No. 3, 7 & 23);
 - b. In order to assert this objection, it requires specificity;
3. DePuy also objects to this interrogatory to the extent that it seeks information regarding components other than the DePuy Summit Femoral Stem, P/N 1570-12-

070, Lot 198547 (the “Subject Component”) implanted during Plaintiff’s August 17, 2012, surgery.

- a. This objection was asserted for interrogatories 1-3, 6. 10, 13-22, 24-25;
- b. This is not even an objection, but a simple refusal to respond about any questions other than Depuy’s Summit Stem that it sold and instructed to be implanted into plaintiff, Jodi;
- c. The only thing close to this is an argument that nothing is relevant except the Depuy Summit Stem, and specifically that stem that was actually implanted into Jodi; not the Biolox Head or the Cup or the liner, or the predecessor devices upon which the subject components were based, etc.

Depuy’s production of documents in response to Plaintiffs’ interrogatories is improper as the documents are not produced as maintained in the ordinary course of business. Moreover, the documents produced are not responsive and are incomplete. Accordingly, Plaintiffs will address inadequacies of Depuy’s document production in its responses to Plaintiffs’ Requests for Production, under separate cover.

Depuy’s Supplemental Productions (dated September 9, and October 21, 2019) in response to Plaintiffs’ Interrogatories are improper. Pursuant to Federal Rules, parties are responsible to fully and completely answer all requests with ALL information then available. Parties are required to supplement answers that were complete upon responding with information or documents that are subsequently created or subsequently come into the party’s possession, custody or control. Notwithstanding, Depuy’s original responses to Plaintiffs’ Interrogatories are clearly incomplete, and the information provided as “supplements” was simply not produced despite its availability. This gamesmanship has interfered with and delayed Plaintiffs’ review of Depuy’s responses and will not be tolerated. Please confirm forthwith that Depuy has fully responded to Plaintiffs’ Interrogatories with all information and documents currently available to Depuy.

Interrogatory No. 1: Depuy’s only objections are boilerplate, and should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which are not limited by Depuy’s objections or self-imposed limitations. Depuy only responded that it manufactures the stem, and does not respond to:

- a. Identify manufacturers of each/all components of implant (not just the stem);
- b. Identify members of distribution chain; and
- c. Provide specific manufacture and distribution information for each product manufactured by Defendant.

Interrogatory No. 2: Depuy’s boilerplate objections should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which are not limited by Depuy’s objections or self-imposed limitations. Further, DePuy’s objection that the discovery requested includes claims which may not be substantially similar to the Plaintiffs’ Complaint is improper and prevents Plaintiffs’ proper discovery.

Interrogatory No. 3: Depuy objects to this interrogatory as vague, ambiguous and overly broad. Depuy's objections, including its boilerplate objections are not appropriate or applicable, and should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which is not limited by Depuy's objections or self-imposed limitations.

Interrogatory No. 4: Depuy's only objections are boilerplate, and should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which is not limited by Depuy's objections or self-imposed limitations.

Interrogatory No. 5: Depuy objects to this interrogatory as compound, ambiguous and overly broad. The boilerplate objections should be withdrawn or overruled. With regard to Depuy's claims of ambiguity or compound questions, the interrogatory clearly requests the following (for which Plaintiffs demand a complete a response that is not limited by Depuy's objections or self-imposed limitations):

5. With regards to the "Summit Tapered Stem" (by whatever brand name or label marketed under) and Biolox head, please:
 - a. Describe the steps of manufacture or assembly;
 - b. Identify when "Summit Tapered Stem" (by whatever brand name or label marketed under) and Biolox head designs were first used;
 - c. Describe the use of porocoat, hydroxyapatite, duofix HA coating, or any other surface alteration or coating which was used, alone or with another surface alteration or coating, and for each coating and combination of coatings identify the dates of use and all surface alterations or coatings applied;
 - i. number of Summit stems with each coating or combination of coatings sold, the years sold, and the gross revenue each year of sale;
 - ii. Identify each person or entity with knowledge of the design or testing of the Summit Stem and describe their responsibility and knowledge; and
 - iii. Identify related documents.

Interrogatory No. 6: Depuy objects to this interrogatory as vague, ambiguous and overly broad. The boilerplate objections should be withdrawn or overruled. Further, Depuy's claims of ambiguity or vagueness regarding "Explant Retrieval Program" are a bad faith attempt to avoid responding. As you obviously would know, Plaintiffs intended to request what is commonly referred to as the "*Implant* Retrieval Program," however, Plaintiffs would propose that the plain meaning, intent and spirit of this interrogatory request would include any Hip Replacement systems, components and parts that were systematically retrieved and/or studied. Plaintiffs demand a complete response to this interrogatory, which is not limited by Depuy's objections or self-imposed limitations.

Interrogatory No. 7: Plaintiffs withdraw Interrogatory No. 7 in compliance with Local Rule 33.3 of the local rules of The Southern District of New York.

Interrogatory No. 8: Depuy's only objections are boilerplate, and should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which are not limited by Depuy's objections or self-imposed limitations.

8. (clarified) Identify the name and period of distribution of each hip replacement system or product that incorporated at any time the Summit Tapered Stem (by whatever brand name or label marketed under), and for each system identify every component part of the product's sub-assembly or assembly which Defendant did manufacture or license to be used under any other product name (including but not limited to Biolox Head) in that system; providing the number of Summit Tapered Stems (by whatever brand name or label marketed under) which were sold singularly (without system) each year, to date; and, the number sold each year with (as part of) Depuy hip replacement systems (including but not limited to Pinnacle, ASR, or others which include a stem, head, liner and cup).

Interrogatory No. 9: Depuy objects to this interrogatory as overly broad, burdensome, vague and confusing. The boilerplate objections should be withdrawn or overruled. With regard to Depuy's claims of vague and confusing, the interrogatory clearly requests the following (for which Plaintiffs demand a complete response that is not limited by Depuy's objections or self-imposed limitations):

9. (clarified) For each Depuy hip replacement system (identified in interrogatory 8, above), provide the 510K numbers, and describe all correspondence or communications with the FDA relating to approvals, denials, clearances, identifying parties and dates to each such communication.

Interrogatory No. 10: Depuy's objections are not well taken should be withdrawn or overruled. Further, Depuy's claims of ambiguity or vagueness are a bad faith attempt to avoid responding. Plaintiffs demand a complete response to this interrogatory, which is not limited by Depuy's objections or self-imposed limitations.

Interrogatory No. 11 & 12: Depuy's only objections are boilerplate and should be withdrawn or overruled. Plaintiffs demand a complete response to these interrogatories, which are not limited by Depuy's objections or self-imposed limitations.

Interrogatory No. 13: Depuy's only objections are boilerplate and should be withdrawn or overruled. Further, Depuy's response was improperly limited to "recalls" and, therefore, incomplete. Plaintiffs demand a complete response to these interrogatories, which are not limited by Depuy's objections or self-imposed limitations.

Interrogatory 14: Depuy's only objections are boilerplate and should be withdrawn or overruled. Plaintiffs demand a complete response to these interrogatories, which are not limited by Depuy's objections or self-imposed limitations.

Interrogatory 15: Depuy's only objections are boilerplate and should be withdrawn or overruled. Plaintiffs demand a complete response to these interrogatories, which are not limited by Depuy's objections or self-imposed limitations.

Interrogatory No. 16: Depuy objects to this interrogatory as overly broad, burdensome and compound. The boilerplate objections should be withdrawn or overruled. With regard to Depuy's claims of compound, the interrogatory clearly requests the following regarding the single subject of applicable standards or regulations (for which Plaintiffs demand a complete response that is

not limited by Depuy's objections or self-imposed limitations):

16. (clarified) Identify Regulations or Standards applicable to the safety of the Defendant's products, including but not limited to the Summit Tapered Stem and the Biolox head

- i. and to which the Defendant claims its components were compliant.
- ii. and to which the Defendant admits its components were not compliant.

And identify each independent laboratory and/or consumer protection group and/or governmental agency which conducted any tests or analysis on the device relating to such compliance or safety, describing the testing performed and any conclusions, results or reports indicating any safety concerns for the product at issue, and the person(s) with knowledge of such testing and safety concerns and the person(s) with custody and knowledge of any responsive documents.

Interrogatory No. 17: Depuy objects to this interrogatory as overly broad, burdensome and compound. The boilerplate objections should be withdrawn or overruled. With regard to Depuy's claims of compound, the interrogatory clearly requests the following regarding the single subject of applicable standards or regulations (for which Plaintiffs demand a complete a response that is not limited by Depuy's objections or self-imposed limitations):

17. (clarified) State whether or not Defendant or any agent, employee, independent contractor or other representative of Defendant is a member of any product, procedure, reliability, quality, safety, testing or standards committees, and/or of any industrial or professional society *which relate to the design, development, manufacture or production of hip replacement systems and components, including but not limited to stem, head, liner and cup*, and please state for each such person or entity: the full name, address, job title, or capacity of each member; the organizations, committees, and sections to which each belongs; and the title, publisher and date of publication of each article or technical paper authored, co-authored, co-authored or sponsored, in whole or in part, by such person or entity.

Interrogatory No. 18: Depuy objects to this interrogatory as overly broad, burdensome and compound. The boilerplate objections should be withdrawn or overruled. With regard to Depuy's claims of compound, the interrogatory clearly requests the following single subject (for which Plaintiffs demand a complete a response that is not limited by Depuy's objections or self-imposed limitations):

18. (clarified) Identify and describe Defendant's policies, procedures, protocols, directives or instructions to its employees, agents, representatives, patients, surgeons, physicians, medical or surgical facilities to record or report adverse incidents regarding Depuy hip prosthesis and their implantation; describe in detail any information or data was to be recorded and/or reported, and the procedure for reporting and maintaining records of such adverse incidents; Identify and describe any and all documents, including

but not limited to internal communications or external correspondence by or between Defendant and others, related to such adverse incidents, and identify the custodian(s) of any such records; Identify and describe any reports created from or relating to such adverse incidents.

Interrogatory No. 19: Depuy objects to this interrogatory as overly broad, burdensome and compound. The boilerplate objections should be withdrawn or overruled. With regard to Depuy's claims of compound, the interrogatory clearly requests the following regarding the single subject (for which Plaintiffs demand a complete response that is not limited by Depuy's objections or self-imposed limitations):

19. (clarified) Identify all documents referring or relating to manufacturing defects, failures and/or flaws in Defendant's hip replacement components or parts which were identified during the product manufacturing, inspection and/or quality control process and identify the custodian of such records for the "Summit Tapered Stem" (by whatever brand name or label marketed under) and/or Biolox head.

Interrogatory No. 20: Depuy's only objections are boilerplate, and should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which are not limited by Depuy's objections or self-imposed limitations.

20. (clarified) Identify any and all documents which refer or relate to complaints, citations, reprimands, warnings, notices, violations or other negative criticism by any government or public entity regarding Defendant's manufacture, design, distribution, safety or informational warnings, advertising, or sale of hip replacement components or parts; Describe Defendant's investigation, findings and responses to each, and identify all documents that refer or relate to such investigation, finding and/or response; and identify the custodian(s) of the documents.

Interrogatory No. 21: Depuy's boilerplate objections should be withdrawn or overruled. Further, Depuy's objection that complaints to and correspondence with the Consumer Product Safety Commission is "irrelevant" is in bad faith and should be withdrawn or overruled. Plaintiffs demand a complete response to this interrogatory, which are not limited by Depuy's objections or self-imposed limitations.

21. (clarified) Identify any adverse incidents referenced, documented or alleged relating to the use of Defendant's hip replacement systems, components or parts, which were reported to any sources other than Depuy (e.g. including but not limited to governmental agencies, Attorney Generals, Consumer Product Safety Commission or other consumer protection or product safety entities, industry or trade entities, and Complaints filed in state or federal Courts); Identify the custodian of such records; and for each Complaint filed in state or federal court, please: (a) identify all such claimants and their attorneys; (b) describe as specifically as possible the product involved, including but not limited to the model and serial numbers; (c) identify all parties, the claimants attorneys, the court in which the complaint was filed; and (d) the case number.

Interrogatory No. 22: Depuy's boilerplate objections should be withdrawn or overruled. Further, Depuy's objection that the request is compound is in bad faith and should be withdrawn.

With regard to Depuy's claims of compound, the interrogatory clearly requests the following regarding the single subject of applicable standards or regulations (for which Plaintiffs demand a complete a response that is not limited by Depuy's objections or self-imposed limitations):

22. (clarified) Identify and describe in detail each test to determine the safety and reliability of the Summit Tapered Stem (by whatever brand name, label or system it was/is marketed under), and the Biolox Head, whether such test was sponsored by Depuy, its agents, representatives, or others, including but not limited to governmental or regulatory agencies. With regard to testing certifications on the subject device, identify each such certification and the name and contact information of the persons/entity involved in such testing, and identify and describe all applications for testing, testing procedures, testing results and reports regarding such compliance testing, including the date(s) of the tests; identify all documents which refer or relate to such testing; and identify the custodian of such documents.

Interrogatory No. 23: Plaintiffs withdraw Interrogatory No. 7 in compliance with Local Rule 33.3 of the local rules of The Southern District of New York.

Interrogatory No. 24: Depuy's boilerplate objections should be withdrawn or overruled. Further, Depuy's objection that the request is compound is in bad faith and should be withdrawn. With regard to Depuy's claims of compound, the interrogatory clearly requests the following regarding the single subject (for which Plaintiffs demand a complete a response that is not limited by Depuy's objections or self-imposed limitations):

24. (clarified) Identify all corporations and entities which were sponsored, paid, employed, or directed by Defendant to participate or engage in the marketing, promotion, advertising, distribution, or sale of the Summit Tapered Stem (by whatever name or label it was marketed or sold), and/or Biolox head and describe in detail each entity's participation; Identify all persons and entities which participated or engaged in the development or publication of information, warnings, promotion, advertisements and representations related to the Defendant's hip replacement systems, including but not limited to the Summit Tapered Stem (by whatever name or label it was marketed or sold) and/or Biolox head, that were published or otherwise intended to reach the customers, patients, surgeons, or physicians, or delivered with the product; and identify each online networking site, social networking site and/or internet blog on which the Defendant, its employees, agents, representatives or anyone acting on behalf of the Defendant (including corporations and entities identified herein) have logged onto and/or participated in regarding the Defendant's hip replacement systems, including but not limited to the Summit Tapered Stem (by whatever name or label it was marketed or sold) and/or the Biolox head, at any time from August 17, 2007 to the present, including but not limited to professional and consumer orthopedic-related sites, Facebook, Twitter, MySpace, Instagram, Pinterest, Vine, Tumblr, Google+, SnapChat, LinkedIn and YouTube, and for each such site provide the name by which the Defendant, or anyone acting on the Defendant's behalf, identified themselves (including display and/or user names) and describe the time period during which such person or entity was a participant or member of the blog.

Interrogatory No. 25: Depuy's boilerplate objections should be withdrawn or overruled. Further, Depuy's objection that the request is compound is in bad faith and should be withdrawn. With

regard to Depuy's claims of compound, the interrogatory clearly requests the following regarding the single subject (for which Plaintiffs demand a complete a response that is not limited by Depuy's objections or self-imposed limitations):

25. (clarified) Identify all documents or materials with information or warnings regarding the were provided or made available to these Plaintiffs prior to or at the time of implantation of the Summit Tapered Stem and/or the Biolox head AUGUST 2012; and which entities (surgeon, patient, hospital, etc.) any such information was provided or made available, and describe the manner in which such information or warnings was made available or delivered.

We have made every effort to explain or clarify any questions you have raised. If you accept and understand the clarifications provided, please confirm within 5 business days and provide complete responses by December 11, 2019. If you do not agree to the resolution or clarification proposed, we will seek a ruling by the court.

/s/ Andre Rouviere

Andre A. Rouviere

AAR/jlr